

KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015
SECTION 1. IDENTIFICATION

Product name : KIT COBAS LIAT FLU A/B & RSV IVD

Product code : 08160104190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road
46250 Indianapolis IN
USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Canada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION
GHS classification in accordance with 29 CFR 1910.1200

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of the workplace.

KIT COBAS LIAT FLU A/B & RSV IVD

Version
1.5

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P285 In case of inadequate ventilation wear respiratory protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
COBAS LIAT INFLUENZA A/B & RSV
GHS Classification

Acute toxicity (Oral)	:	Category 4
Acute toxicity (Inhalation)	:	Category 4
Skin corrosion	:	Category 1B
Serious eye damage	:	Category 1
Respiratory sensitization	:	Category 1
Skin sensitization	:	Category 1

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
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KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Thiocyanic acid, compd. with guanidine (1:1)	593-84-0	>= 30 - < 50
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9	>= 1 - < 5
Proteinase K	39450-01-6	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Consult a physician.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : Call a physician or poison control center immediately.
Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NO_x)
Sulfur oxides
Hydrogen cyanide (hydrocyanic acid)
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Ensure adequate ventilation.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : Avoid formation of aerosol.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not

KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

be employed in any process in which this mixture is being used.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Technical measures/Precautions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
COBAS LIAT INFLUENZA A/B & RSV
Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Proteinase K	39450-01-6	IOEL	0.00006 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Impervious clothing
Choose body protection according to the amount and con-

KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

centration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
COBAS LIAT INFLUENZA A/B & RSV

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)
Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : Hazardous decomposition products formed under fire conditions.

KIT COBAS LIAT FLU A/B & RSV IVD

Version
1.5

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Toxic gases may be released if in contact with the following:
sodium hypochlorite
Acids
Strong oxidizing agents
No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : Strong acids
Strong oxidizing agents
Cyanides
sodium hypochlorite

Hazardous decomposition products : In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides
Hydrogen cyanide (hydrocyanic acid)

SECTION 11. TOXICOLOGICAL INFORMATION
COBAS LIAT INFLUENZA A/B & RSV
Acute toxicity

Harmful if swallowed or if inhaled.

Ingredients:
Thiocyanic acid, compd. with guanidine (1:1):

Acute oral toxicity : LD50 Oral (Rat): 593 mg/kg
Symptoms: Vomiting

Acute inhalation toxicity : Acute toxicity estimate: 1.5 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgment

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Acute oral toxicity : LD50 Oral (Rat): > 6,730 mg/kg
LD50 Oral (Rabbit): > 7,000 mg/kg
LD50 Oral (Mouse): 5,400 mg/kg

Skin corrosion/irritation

Causes severe burns.

Ingredients:**Thiocyanic acid, compd. with guanidine (1:1):**

Result : Causes burns.

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Remarks : May cause skin irritation in susceptible persons.

Proteinase K:

Result : Irritating to skin.

Remarks : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Causes serious eye damage.

Ingredients:**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

Proteinase K:

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingredients:**Proteinase K:**

Assessment : May cause sensitization by skin contact.

Remarks : Causes sensitization.

Assessment : May cause sensitization by inhalation.

Germ cell mutagenicity

Not classified based on available information.

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**Carcinogenicity**

Not classified based on available information.

Ingredients:**Thiocyanic acid, compd. with guanidine (1:1):**

Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.**Reproductive toxicity**

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Ingredients:**Proteinase K:**

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Proteinase K:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Ingredients:****1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**NOAEL : 4,000 mg/kg
Exposure time : 5d
Number of exposures : 1**Aspiration toxicity**

Not classified based on available information.

Ingredients:**Proteinase K:**

No data available

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

SECTION 12. ECOLOGICAL INFORMATION**COBAS LIAT INFLUENZA A/B & RSV****Ecotoxicity****Ingredients:****Thiocyanic acid, compd. with guanidine (1:1):**Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l
Exposure time: 96 hNOEC (Poecilia reticulata (guppy)): 25 mg/l
Exposure time: 96 hToxicity to daphnia and other : EC50 (Daphnia): 42.4 mg/l
aquatic invertebrates Exposure time: 48 hNOEC (Daphnia magna (Water flea)): 6.25 mg/l
Exposure time: 48 h**Ecotoxicology Assessment**

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment**1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**

Toxicity to fish : LC0 (Carassius auratus (goldfish)): 625 mg/l

Toxicity to daphnia and other : LC100 (Daphnia magna (Water flea)): 85 mg/l
aquatic invertebrates

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): 640 mg/l

Toxicity to microorganisms : EC0 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015**Proteinase K:****Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability**Ingredients:****1,2,3-Propanetricarboxylic acid, 2-hydroxy-:**Biodegradability : Biodegradation: 98 %
Exposure time: 7 d
Method: OECD Test Guideline 302B**Bioaccumulative potential****Ingredients:****Thiocyanic acid, compd. with guanidine (1:1):**

Partition coefficient: n-octanol/water : log Pow: -1.38

1,2,3-Propanetricarboxylic acid, 2-hydroxy-:

Partition coefficient: n-octanol/water : log Pow: -1.72

Proteinase K:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**COBAS LIAT INFLUENZA A/B & RSV****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

Glycine

56-40-6

>= 1 - < 5 %

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Thiocyanic acid, compd. with guanidine (1:1)
non hazardous compounds (liquid)
1,2,3-Propanetricarboxylic acid, 2-hydroxy-

593-84-0
Not Assigned
77-92-9

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. non hazardous compounds (liquid) Proteinase K
AICS	:	Not in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Not On TSCA Inventory

KIT COBAS LIAT FLU A/B & RSV IVD

Version
1.5

Revision Date:
08-02-2018

Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

COBAS LIAT INFLUENZA A/B & RSV
GHS label elements

Hazard pictograms



Signal Word

: Danger

Hazard Statements

: H302 + H332 Harmful if swallowed or if inhaled.
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H317 May cause an allergic skin reaction.
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Precautionary Statements

: **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a

KIT COBAS LIAT FLU A/B & RSV IVD
Version
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

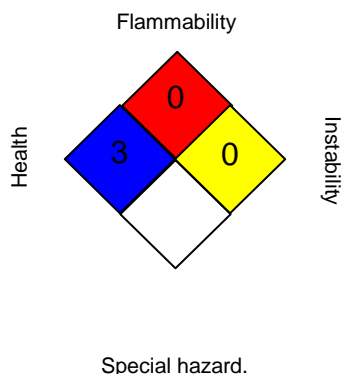
POISON CENTER/doctor.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION
Further information**COBAS LIAT INFLUENZA A/B & RSV****NFPA:****HMIS® IV:**

HEALTH	*	3
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Pre-

KIT COBAS LIAT FLU A/B & RSV IVDVersion
1.5Revision Date:
08-02-2018Date of last issue: 06-18-2018
Date of first issue: 12-09-2015

vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-02-2018

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1711